DISCUSSION PAPER

Managing Food Innovation: Novel Foods, Ingredients and Processes – Food Regulatory Practices and the Role of Codex

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1. Background

Novel foods, ingredients, and processes—including those derived from emerging technologies such as precision fermentation, cellular agriculture, nanotechnology, and advanced processing methods—are reshaping the global food landscape. They hold the promise of diversifying food sources, improving sustainability, and addressing nutritional needs. Yet, for regulators, these innovations present complex challenges: assessing safety where there is limited history of consumption, developing fit-for-purpose risk assessment approaches, and harmonizing definitions and standards across jurisdictions.

For innovators, the absence of clear, predictable regulatory pathways can delay market entry, increase costs, and create uncertainty for investment. As national systems respond in different ways—ranging from bespoke novel food approval processes to integration within existing frameworks—the lack of global alignment risks creating trade barriers and uneven consumer protection. **Establishing more predictable, transparent, and science-based regulatory environments**, supported by international guidance through Codex, is essential to foster innovation while ensuring safety and maintaining fair practices in the food trade.

2. Relevance to Codex

At its 46th Session (Rome, 27 November – 2 December 2023), the Codex Alimentarius Commission (CAC) considered how to address “New Food Sources and Production Systems” (NFSPS), encompassing novel foods, ingredients, and processes. This discussion followed earlier debates in CAC44, CAC45, and the Executive Committee, and a targeted consultation under CL 2023/31, which revealed two broad perspectives: one supporting the establishment of a dedicated, cross-cutting mechanism (such as an ad hoc task force or electronic working group) to address NFSPS, and another affirming that existing Codex structures and procedures are sufficient. Members and observers identified a wide

range of NFPS topics potentially requiring Codex attention—from edible insects, algae-based foods, cell-based products, and precision fermentation to nanotechnology applications and 3D-printed foods—and cited challenges such as lack of common definitions, regulatory heterogeneity, and potential trade barriers.

CAC46 concluded that there are currently no procedural impediments to submitting new work on NFSPS to existing committees or directly to CCEXEC and CAC, and encouraged Members to bring forward concrete, science-based proposals or discussion papers. The Commission agreed that the most appropriate time to consider creating a new, dedicated mechanism would be when there is greater clarity on the specific work required, while continuing to rely on Codex's horizontal committees, established risk analysis principles, and existing pathways for new work. This approach reflected a pragmatic balance—ensuring readiness to address emerging technologies without adding new structures prematurely, while keeping open the option to establish a dedicated body should the scope and complexity of NFSPS-related work demand it.

3. Relevance to CCASIA Countries

For the Asia region, and CCASIA countries in particular, novel foods and processes present both significant opportunities and pressing regulatory challenges. The region is home to dynamic food innovation ecosystems—spanning alternative proteins, algae-based products, functional ingredients, and advanced processing technologies—driven by strong consumer demand, export ambitions, and investment in agri-food technology. At the same time, regulatory approaches to novel foods remain highly variable across CCASIA members, **with differences in definitions, pre-market approval requirements, and data expectations**. Such divergence can slow intra-regional trade, limit access to export markets, and undermine investor confidence. Given that many CCASIA economies are both importers and exporters of novel food products, **the absence of a predictable, harmonized approach increases the risk of market fragmentation.** Leveraging Codex as a platform to exchange regulatory experience, identify common principles, and align on science-based risk assessment approaches would strengthen consumer protection, facilitate trade, and position CCASIA countries as active contributors to shaping global guidance in this rapidly evolving field.

4. Discussion and Consideration for Collaborative Action

4.1 Novel Food and Innovation

Novel foods and processes encompass a wide spectrum of innovations that extend beyond traditional agricultural and food production systems. While definitions vary among jurisdictions, these generally include:

- **Novel ingredients –** these include **substances with no history of safe use** in a given market, such as certain algae species, phytochemicals, or bioactive compounds, as well as **ingredients derived from known or traditional foods but presented in a new form**. In the latter case, the mode of production, extraction, concentration, or formulation alters their pattern of presence in the diet-for example, bioactive compounds concentrated from plants, peptides produced through novel enzymatic processes, or ingredients manufactured via fermentation or synthetic biology. In both situations, novelty may arise from changes in composition, bioavailability, or exposure levels compared to traditional dietary patterns, creating a need for specific safety assessment before market entry.

- **Novel production systems** – including cell-based (cultivated) meat, dairy, and seafood; fermentation-derived proteins; and genetically modified or gene-edited organisms developed for food use.
- **Novel processes and technologies** – such as high-pressure processing, pulsed light treatment, nanotechnology applications, and 3D food printing, particularly when they alter food structure, composition, or safety considerations in ways not previously evaluated.
- **Novelty in food or ingredient attributes** – where the uniqueness lies not in the source or process, but in the resulting physiological or functional effect on the human body. Examples include foods or ingredients with newly demonstrated bioactive properties, modified nutrient bioavailability, or targeted metabolic effects. Determining this type of novelty often requires assessing evidence from clinical studies, bioavailability trials, or validated biomarkers. Qualification involves establishing the plausibility and significance of the claimed effect, its potential benefits or risks, and whether such effects warrant additional pre-market evaluation to ensure safety and accuracy in labelling or marketing.

These innovations promise benefits in **sustainability, resource efficiency, nutrition, and consumer choice**. However, they also introduce regulatory complexities. **A core challenge lies in safety assessment**: the absence of established consumption history requires rigorous data on toxicology, allergenicity, nutritional equivalence, and manufacturing controls. Risk assessment methodologies must often adapt to novel endpoints, while maintaining Codex's principles of transparency, reproducibility, and reliance on sound science.

Equally important is the **regulatory predictability** needed by innovators. Divergent definitions of "novel food," varying pre-market approval requirements, and inconsistent data acceptance criteria can deter investment, delay market entry, and complicate trade. For regulators, rapidly evolving innovation pipelines create pressure to evaluate new products efficiently without compromising consumer protection. This demands regulatory frameworks that **are agile**—able to **integrate new scientific evidence**, learn from international experience, and provide clear guidance to applicants.

4.2 Opportunities for Collaboration and Regulatory Convergence

While it is recognized that not all elements—such as the precise definition of "novelty" or "novel food"—may be fully amenable to global harmonization, there are areas where Codex could play a pivotal role in promoting convergence. These include developing common guidance on data requirements, establishing shared risk assessment methodologies, and fostering combined resources and collaborative mechanisms to support regulatory decision-making. Such efforts could help build mutual confidence among authorities, reduce duplication of work, and facilitate more efficient market access for safe, innovative products.

In this context, the role **of food regulatory cooperation**, including under the auspices of Codex may be described as twofold:

- **Harmonization of principles** – ensuring that safety assessment and regulatory decision-making for novel foods and processes are guided, where feasible, by **common definitions**, **transparent procedures**, and science-based criteria, and supported by agreed methodologies and evidence standards.

- **Facilitation of mutual confidence** – enabling regulators to recognize and, where appropriate, rely on assessments conducted by other competent authorities, thereby reducing duplication and accelerating safe market access.

4.3 Practical Considerations for CCASIA Collaborative Mechanisms

There is a strong and timely opportunity for **CCASIA members** to take a proactive and coordinated leadership role in translating the principles of harmonization and mutual confidence into practical action for the region. For those categories of **novel foods or processes where market demand** and **regulatory interest** are greatest, CCASIA could serve as a dedicated regional platform to:

- **Develop common guidelines for safety assessment**, including harmonized data requirements, standardized formats for submission, and clear procedural timelines.
- **Pursue collaborative safety assessment approaches**, such as joint reviews or coordinated data generation initiatives, where the resulting assessments could be recognized by multiple countries in the region.
- **Enable shared access to assessment outcomes**, so that participating Members can benefit directly from work already completed, reducing duplication of effort and lowering costs.

For applications **requiring wider international engagement and recognition**, CCASIA could also act as a bridge to Codex, identifying the most appropriate structures to address such work—whether through existing committees or, where warranted for **specific product categories**, the establishment of **an intergovernmental task force**. Such a task force could be supported by ad hoc expert consultations convened by FAO/WHO to conduct international risk assessments, building on data already generated through prior collaborative regional efforts.

This approach would allow CCASIA to not only contribute substantively to Codex deliberations, but also to **accelerate the standardization of novel foods, functional ingredients, and novel processes**. By positioning itself at the forefront of designing and implementing coordinated safety assessment frameworks, CCASIA can ensure that the region is not a passive recipient of global standards, but an **active driver shaping them**—linking regional priorities to global standard-setting and influencing the Codex agenda in areas of strategic importance.

5. Conclusion

By fostering shared and consistent terminology, encouraging the exchange of regulatory experiences, and **developing guidance that is firmly anchored in Codex's risk analysis framework**, Members can create an enabling environment for innovation while safeguarding public health.

For these efforts to succeed, actions and interventions must remain firmly rooted in Codex principles and values—transparency, inclusiveness, scientific rigor, and consensus-building. Upholding these foundations will be essential to ensuring that novel foods, ingredients, and processes realize their potential to contribute to safe, sustainable, and resilient food systems, both within the CCASIA region and globally.

Annex 1: Summary Overview of Food Regulatory Environment Surrounding Novel Food and Processes

Regulatory approaches to novel foods vary widely across jurisdictions, but share the common objective of ensuring consumer safety, fair practices in food trade, and informed choice. Most frameworks cover three interrelated dimensions:

1. Novel Food Ingredients

- **In the European Union**, Regulation (EU) 2015/2283 defines "novel food" as food not consumed to a significant degree in the EU before 15 May 1997, including newly developed, innovative foods, and those produced using new technologies or processes. Pre-market authorization is required, supported by a comprehensive safety dossier evaluated by the European Food Safety Authority (EFSA).
- **Canada** regulates novel foods under the Food and Drug Regulations, defining them broadly to include foods with no history of safe use, foods resulting from genetic modification, and foods manufactured using novel processes. Safety assessments consider composition, nutritional impact, toxicology, and allergenicity.
- **Singapore** applies a "novel food" definition to foods without a history of safe use in the country and requires a pre-market safety assessment by the Singapore Food Agency (SFA). The framework includes specific guidance for cultivated meat and microbial proteins.

2. Claims on Novel Foods or New Food Attributes / Functionality

- Claims associated with novel foods, particularly nutrition and health claims, are subject to additional scrutiny. In the EU, Regulation (EC) No 1924/2006 requires that claims be scientifically substantiated and authorized before use.
- In markets like **Australia/New Zealand**, the Food Standards Code mandates pre-approval for high-level health claims and demands evidence of efficacy and safety for functional components.
- Many jurisdictions link the authorization of claims to the safety assessment of the ingredient itself, meaning a novel ingredient cannot carry a health claim unless both the ingredient and the claim have been assessed and approved.

3. Novel Processes and Technologies

- *Novel processes*—such as high-pressure processing, pulsed electric fields, nanotechnology, and precision fermentation—are regulated either as part of the novel food definition (EU, Canada) or under specific technology-related provisions (e.g., Japan's Food Sanitation Act for nanomaterials).
- Some jurisdictions, such as Japan and Korea, have developed specific guidance for foods produced using new biotechnologies, often aligning with Codex principles for risk analysis of foods derived from modern biotechnology.
- For processes that alter food safety or nutritional characteristics significantly, regulatory authorities generally require process validation data, hazard identification, and where necessary, toxicological evidence.

Global Trends

While definitions and procedural details differ, there is an emerging trend toward:

- Risk-based, case-by-case assessments guided by Codex principles.
- Increased transparency and public access to evaluation reports.
- Development of specific guidance for high-profile innovations (e.g., cell-based meat, precision fermentation).
- Movement toward mutual recognition or reliance mechanisms, particularly among trade partners.

This diversity of approaches underscores the importance of Codex's role in providing internationally agreed principles and guidance to facilitate convergence, avoid duplication, and support safe and equitable market access for novel foods and processes.